

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

REMARKS

The Office Action mailed March 7, 2006, has been carefully reviewed and Applicants note with appreciation the identification of allowed subject matter.

By this Amendment, Applicants have amended claim 1, and added claim 28. Claims 1, 3-7, 9-13, 15, 17-19 and 21-28 are pending in the application, and claims 1, 25, 26, 27 and 28 are independent. In view of the above amendments and the following remarks, favorable reconsideration is respectfully requested.

The Examiner rejected claims 1, 3-6, 9, 11-13, 17, 21, 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,376,067 to Daneshvar in view of U.S. Patent No. 6,168,800 to Dobos along with WO 93/01777 to Malloul. Also under 35 U.S.C. 103(a), the Examiner rejected claim 10 as being unpatentable over Daneshvar in view of Dobos and Malloul and further in view of U.S. Patent No. 5,181,905 to Flam, and rejected claim 15 as being unpatentable over Delmore in view of U.S. Patent No. 6,168,800 to Dobos, and rejected claim 15 as being unpatentable over Daneshvar in view of Dobos and Malloul and further in view of U.S. Patent No. 6,384,293 to Marcussen. Claims 7, 18, 19 and 22 were objected to as being dependent on a rejected base claim, but the Examiner stated that claims 7, 18, 19 and 22 would be allowable if rewritten in independent form including all of the limitations

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

of the base claim and any intervening claims. Claims 25-27 are allowed.

Claim 1 has been amended to clarify that the "insetting" of the absorbent element is with respect to the *thickness* of the pressure distributing element, i.e., the insetted portion extends in a generally perpendicular direction with respect to the skin-contacting surface.

As was explained in detail in the previous Amendment filed on December 27, 2005, and evidentially supported by the Declaration of Truels Sterm Larsen (hereafter "Mr. Larsen's Declaration") filed concurrently therewith, the present invention is directed to a pressure *relieving* dressing for a wound. The dressing has an absorbent element *inset within* a pressure distributing element, with both elements being in contact with the skin when the dressing is applied. The insetting of the absorbent element *within the thickness* of the pressure distributing element results in the absorbent element extending, *from its skin-contacting surface*, at least partly *through the thickness* of the pressure distributing element. This is not shown by Daneshvar.

Daneshvar teaches, without any ambiguity, a pressure *applying* dressing. As stated in the first sentence of the abstract, Daneshvar is directed to "pressure bandages [that] use a balloon for applying pressure to a wound". This is repeated in the

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

summary of the invention at column 1, lines 43-45, "This invention combines pressure applied by a balloon with a dressing to prevent bleeding after procedures", and at lines 54-56, "the balloon is to press the wound with use of appropriate pressure to prevent bleeding". Clearly, this is in direct opposition to the pressure *relieving* dressing being claimed by the present invention.

That a pressure *applying* dressing and a pressure *relieving* dressing are diametrically opposed to one another in purpose and function is substantiated by Mr. Larsen's Declaration. As stated in paragraph 3 thereof, the pressure relieving dressing as currently claimed is aimed at distributing pressure away from a wound, and *not* at applying pressure to the wound, being "especially important for pressure sores" to which, of course, one would not want to apply further pressure. This is clearly not analogous to the pressure applying function and structure taught by Daneshvar. In fact, the known distinctiveness of the two wound treatment protocols is directly addressed by paragraph 7 of Mr. Larsen's Declaration:

Prior to my invention, it was known in the dressing art to apply pressure to certain types of wounds in order to reduce bleeding and facilitate healing. Conversely, wounds actually caused by undue or long term pressure must be handled differently, needing not the application of pressure but rather a pressure distributing construction to relieve the injured area.

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

Turning to the Examiner's discussion of Daneshvar, Applicants are not certain as to the specific embodiment being relied upon, as reference is made to Figures 5 and 6 in conjunction with a discussion of absorbent element 42 and pressure distributing element 45, neither of which appear in Figures 5 or 6. Instead, Figures 5 and 6 disclose a pressure applying balloon 7 covered with gauze 8 and held against the wound by the adhesive film 10 on back part 9 (see column 3, lines 12-27). There is no pressure relieving component.

The Examiner then refers to column 14, lines 5-11, as describing a pressure distributing element made of a material that distributes both static pressure and sudden impacts. This text section discusses Figures 15 and 16 (which also do not show an absorbent element 42 and pressure distributing element 45), illustrating another embodiment of the same pressure applying construction taught throughout Daneshvar. Specifically, the main piece 27 with balloon 7 is used to apply pressure to the site of a herniorrhaphy. The strap 28, 29, 30 and 32 does not distribute pressure but provides the means of drawing the balloon inwardly against the wound to ensure the application of pressure.

Finally, while not identified by the Examiner, Figures 17 and 18 illustrate a balloon 42, an absorbent component 43 and a strap 45, which is the nearest correlation Applicants can find with

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

the cited absorbent element 42 and pressure distributing element 45. However, as in all of the embodiments of Daneshvar, this dressing *applies* pressure by pressing the balloon 41, 42 against the wound and securing it in place using the strap, as shown in Figure 19. As in the previous embodiment of Figures 15 and 16, the strap 45 does not distribute pressure but provides the means of drawing the balloon inwardly against the wound to ensure the application of pressure.

Since Daneshvar is directed to an entirely different wound treatment protocol, as clearly stated therein and as distinguished in type by Mr. Larsen's Declaration, none of the embodiments of Daneshvar can or do disclose or suggest a pressure *relieving* dressing. Further, since there is no pressure distributing element in Daneshvar, Daneschvar cannot and does not disclose an absorbent element that is at least partially inset within the thickness of such a pressure distributing element. To the contrary, there is no way for the absorbent element or gauze of Daneshvar to be "inset" within the thickness of the pressure applying balloon. And to inset the balloon within the holding strap would reduce the desired pressure applying capability of the balloon, contrary to the clear teaching of Daneshvar.

Dobos also does not provide the necessary teaching to render claim 1 obvious in combination with Daneshvar. Dobos

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

teaches an anti-microbial multi-layer island dressing, not a pressure relieving dressing. The absorbent element 44 is not part of the skin contacting surface but is specifically identified as being sealed within an interior reservoir compartment 48 formed by outer layer 42 and first layer 40 (see column 10, lines 32-37). Hence, the absorbent layer cannot extend from the skin-contacting surface at least partly through the thickness of a pressure distributing element, as claimed by the present invention.

Finally, Malloul also does not teach an absorbent element that extends *from the skin contacting surface* at least partly through the thickness of the pressure distributing element. Instead, Malloul teaches an inelastic support 1 having an absorbent or padded element 3 positioned *between* two shock-absorbing pads 4. The shock absorbing pads 4 engage healthy skin on either side of a wound while defining a free intermediate space that surrounds the wound *without touching it* (see the Abstract). Thus, while the element 3 *spans the distance between* the pads 4 it cannot be said that the padded element 3 extends *into or through the thickness* of the shock-absorbing pads 4. Nor is there anything to suggest insetting of the absorbent element 3 so that it extends from the skin into the thickness of the pressure distributing pads as this would both interfere with the disclosed manner in which the

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

dressings is secured to the healthy skin by adhesive portion 2, and also be in contradiction to the express purpose of protecting the wound from contact.

Nor would there be any motivation or logical reason to combine Malloul with Daneshvar. Daneshvar is premised on the desirability of applying direct pressure to a wound to reduce bleeding and facilitate healing. Malloul does the opposite, avoiding contact with the wound, with the absorbent element spaced therefrom. Given these fundamental differences, Malloul and Daneshvar cannot be logically combined to render claim 1 obvious.

In view of the foregoing, as well as Mr. Larsen's Declaration already of record, Applicants respectfully and earnestly request the Examiner's reconsideration and withdrawal of the rejection and allowance of claim 1.

Claims 3-7, 9-13, 15 and 17-19 and 21-24 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein. Particularly, claims 7, 18, 19 and 22 are allowable in accordance with the Examiner's identification of allowable subject matter therein. Claims 25-27 are allowed.

New claim 28 represents the subject matter of claim 7 rewritten in independent form to substantially include the

Serial No.: 09/926,293
Atty. Docket No.: P67157US0

limitations of the underlying claims and is in condition for allowance in accordance with the Examiner's identification of allowable subject matter therein.

Accordingly, with this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By *Harvey B. Jacobson, Jr.* Reg. No. 40,455
HBJ Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, NW
Washington, D.C. 20004-2201
Telephone: (202) 638-6666
Date: August 3, 2006
HBJ:SCB

R:\SBAILEY\08-06\P67157US.amd